Statement of Senator Dianne Feinstein

Senate Committee on the Judiciary

"Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act"

December 12, 2017

As Delivered

Thanks very much, Mr. Chairman. I'm very disappointed that neither the DEA nor Justice Department would allow DEA Chief Administrative Law Judge Mulrooney, who wrote a law review article that was critical of the law, to testify. In that regard I'm going to put in the record a letter dated December 12th from an assistant Attorney General who didn't bother to sign it himself, and I can't make out the handwriting of the person who did, but essentially saying that we have other people and they will not make him available. It's the first time in 25 years, I've had this kind of thing, where somebody we wanted to be a witness, was not permitted to come before the committee

Today we are confronted with three indisputable facts:

1. we are in the midst of an opioid epidemic, the likes of which this country has never seen;
2. we have a collective responsibility to better address it; and
3. Clearly, law enforcement can't keep up with it.

Recent news reports claim that this bill, which was enacted in 2016, is partially to blame for this struggle.

This law does four things, and let me point them out. It outlines the conditions that must be met by drug manufacturers and distributors in order to obtain a DEA registration.

Two, it defines "imminent danger to the public health or safety." In doing so, it lays out the circumstances under which DEA may issue an order to show cause, an immediate suspension order, or revoke a registration.

These circumstances were not previously defined, which left registrants unsure of when DEA might take action against them. This point was underscored in a 2015 GAO report, which made three recommendations to DEA about how to improve communication with registrants in order to ensure better compliance with this law. DEA has not yet implemented these recommendations. That's my understanding.

Third, the law allows registrants to submit a corrective action plan prior to DEA revoking or suspending their registrations. However, it also stipulates that when an imminent danger exists, DEA may immediately suspend a registration, even if the registrant submits a correction action plan.

Finally, the law required the Department of Health and Human Services to report to Congress on how law enforcement can better collaborate with the pharmaceutical industry to increase patient access and prevent drug diversion. The Department is eight months late in submitting this report, and it has failed to respond to the inquiry the Chairman and I made about it.

Data provided by DEA does not seem to support the argument that this law has hindered its enforcement efforts. To the contrary, it shows that DEA enforcement actions – while now starting to increase – began declining well before this law was enacted.

Between 2011 and 2016, immediate suspension orders filed against pharmacies went from 21 to 4, and those filed against practitioners went from 43 to 5. The last time an immediate suspension order was filed against a manufacturer or distributor – and this order immediately stops the distribution of pills – was, guess what? In 2012.

Between 2010 and 2016, civil penalties levied against distributors dropped from $3.1 million to a mere $115,000. Sounds to me, like something isn't working.

So, during the same years that we saw opioid overdose deaths increase by 57 percent, DEA's enforcement actions in many categories substantially declined.

What I want to know, is why? Something isn't working, and needs to be fixed. If it is not the law – and I've asked DEA and the Justice Department for their assistance in looking at the law – then we need to figure out where the problems lie.

I have been struck by the examples of negligent distributors raised in recent hearings and roundtables. Let me give you an example. In a two year period, nearly 9 million opioids were delivered to a single pharmacy in West Virginia. Nine million pills, to a single pharmacy, in a small state, West Virginia. Further, between 2007 and 2012, distributors delivered 780 million oxycodone and hydrocodone pills to pharmacies throughout that state.

The result? A reported $17 billion profit for distribution companies, and here's the price: 1,728 fatal overdoses over six years. One thousand, seven hundred and twenty-eight fatal overdoses versus a $17 billion profit for distributors.

Consequently many distributors faced and settled lawsuits with the state. Yet almost all of them maintain that prescribers, pharmacies, and law enforcement are better situated than they are to prevent diversion.

It is hard to imagine a circumstance under which a request for 9 million pills to a single pharmacy or 780 million pills to a single state would not set off warning bells to those distributing them. In my judgement, there was no excuse for the continued shipment of these drugs.

The regulations promulgated by the Controlled Substances Act require manufacturers and distributors to conduct due diligence of their customers; to detect and disclose suspicious orders

to DEA; and to keep complete and accurate records relating to the manufacture or distribution of controlled substances.

It may well be that DEA needs to issue more guidance as to what constitutes a suspicious order, but these examples illustrate the fact that some distributors appear to be more concerned about their bottom line than fulfilling their responsibilities under this law. Bottom line: we can't turn a blind eye to this kind of reckless disregard, and law enforcement must actively pursue these kinds of cases.

With that, I look forward to hearing from our witnesses about how and whether this law should be modified. We cannot continue, ladies and gentlemen, to lose more than 33,000 Americans each year to an epidemic that's entirely preventable.

Thank you, Mr. Chairman.

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